

EXHIBIT 1

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

**Medicare Reimbursement
of Prescription Drugs**



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EXECUTIVE SUMMARY

PURPOSE

This inspection compares Medicare reimbursement for prescription drugs to costs incurred by the Department of Veterans Affairs, the physician/supplier community, and Medicaid.

BACKGROUND

Medicare does not pay for most outpatient prescription drugs. However, Medicare Part B will cover certain prescription drugs under specific circumstances. Medicare and its beneficiaries paid \$3.9 billion for prescription drugs in 1999. The Health Care Financing Administration (HCFA) requires its local carriers and four durable medical equipment regional carriers (DMERCs) to establish reimbursement amounts for covered drugs. In general, the Medicare reimbursement amount for a covered drug is 95 percent of the drug's average wholesale price (AWP). Of this amount, Medicare pays 80 percent while the beneficiary is responsible for a 20 percent copayment.

Each State Medicaid agency has the authority to develop its own drug reimbursement methodology subject to upper limits set by HCFA. Additionally, Medicaid receives rebates from drug manufacturers as required by Federal law. Unlike Medicare and Medicaid, the Department of Veterans Affairs (VA) purchases drugs for its healthcare system directly from manufacturers or wholesalers. Physicians and suppliers can purchase drug products through closed pharmacies, group purchasing organizations, wholesalers, and directly from manufacturers.

For 24 drugs with the highest total Medicare payments in 1999, we compared Medicare's current reimbursement amount for each drug to prices available to the VA and the physician/supplier community, as well as to Medicaid rebate amounts.

FINDINGS

Medicare and its beneficiaries would save \$1.6 billion a year if 24 drugs were reimbursed at amounts available to the VA

After comparing the median Medicare reimbursement amount with the corresponding median VA acquisition cost for 24 drugs, we estimated that Medicare and its beneficiaries would save \$1.6 billion a year if the Medicare reimbursement amounts for the drugs equaled prices obtained by the VA under the Federal Supply Schedule. The estimated savings represents 52 percent of the \$3.1 billion in reimbursement that Medicare and its beneficiaries paid for these 24 drugs in 1999. The VA paid between 8

and 91 percent less than Medicare for the 24 drugs reviewed. Medicare paid more than double the VA price for 12 of the reviewed drugs.

Medicare and its beneficiaries would save \$761 million a year by paying the actual wholesale price for 24 drugs

We estimated that Medicare payments for 24 drugs exceeded actual wholesale prices by \$761 million a year. This represents 25 percent of the \$3.1 billion Medicare and its beneficiaries paid for these drugs in 1999. Actual wholesale prices were between 6 and 84 percent below Medicare reimbursement amounts for the 24 drugs. Four of the drugs had median catalog prices that were less than half the Medicare amount. One of these drugs had a Medicare reimbursement amount more than six times higher than the median catalog price.

Medicare would save over \$425 million a year on 24 drugs by obtaining rebates equal to those in the Medicaid program

We estimated that Medicare would save \$429 million a year on the 24 reviewed drugs by collecting rebates equal to those negotiated by the Medicaid program. These rebates would lower Medicare spending on these 24 drugs by almost 15 percent.

Carriers are not establishing consistent drug reimbursement amounts for certain drugs

Although Medicare's reimbursement methodology states that drugs are reimbursed at 95 percent of AWP, we found differences in drug reimbursement amounts between local carriers. Six of the 21 drugs whose reimbursement amounts are set by local carriers had more than a 10 percent difference between the lowest and highest reimbursement amount. The most egregious was J0640 (leucovorin calcium), with one carrier reimbursing \$17.51 and another reimbursing \$35.47. The variation in reimbursement amounts was not present for the three drugs reimbursed by DMERCs.

RECOMMENDATIONS

The HCFA should reduce excessive Medicare drug reimbursement amounts

Despite numerous attempts by HCFA to lower Medicare drug reimbursement, the findings of this report illustrate once again that Medicare simply pays too much for prescription drugs. The published AWP that Medicare carriers currently use to establish reimbursement amounts bear little or no resemblance to actual wholesale prices that are available to physicians, suppliers, and other large government purchasers. We believe that HCFA's attempts to use the more accurate AWP supplied by First Databank, publisher of a drug pricing compendium used by the drug industry, is a significant first step towards reimbursing drugs in a more appropriate manner. However, we believe that HCFA should continue to seek additional administrative and legislative remedies to reduce excessive drug reimbursement amounts.

We believe there are a number of options available to HCFA for implementing this recommendation, including: (1) continuing to collect more accurate average wholesale prices from drug pricing catalogs, (2) basing payment on physician/supplier acquisition costs, (3) establishing manufacturers' rebates similar to those used in the Medicaid program, (4) creating a fee schedule for covered drugs based on Department of Veterans Affairs prices, and (5) utilizing the inherent reasonableness authority.

The HCFA should require all carriers to reimburse a uniform amount for each drug

We believe that the pricing differences among local carriers for individual drug codes is problematic. The amount which physicians and suppliers are reimbursed for drugs should not depend on which carrier they bill. The DMERCs have been able to adopt uniform pricing for the drugs which they cover, and we expect that local carriers should be able to do the same. In a 1997 report which noted similar problems, we recommended two options to correct pricing differences: (1) the HCFA could supply all carriers with list of average wholesale prices that it has determined represent each drug code, or (2) the HCFA could contract with a single entity to calculate drug reimbursement amounts and then distribute the amounts to each carrier. We continue to recommend that HCFA undertake one of these options.

Agency Comments

The HCFA concurred with our recommendation that reimbursement amounts for Medicare-covered drugs should be lowered, noting that the current AWP-based reimbursement method creates incentives for price inflation, distorts clinical decisions, and cheats taxpayers. The HCFA also explained that some providers now rely on inflated drug payments to cover other practice expenses. The HCFA believes that any price reductions need to take these expenses into account. Nevertheless, the HCFA strongly agreed that the payment of inflated drug prices is an inappropriate way to compensate practitioners and suppliers for inadequate reimbursement of other practice costs. The HCFA also agreed with our recommendation that Medicare carriers should be required to reimburse uniform amounts for covered drugs. The full text of HCFA's comments is presented in Appendix F.

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INTRODUCTION

PURPOSE

This inspection compares Medicare reimbursement for prescription drugs to costs incurred by the Department of Veterans Affairs, the physician/supplier community, and Medicaid.

BACKGROUND

Medicare Drug Reimbursement

Medicare does not pay for over-the-counter or most outpatient prescription drugs. However, under specific circumstances, Medicare Part B covers drugs used with durable medical equipment (DME) or infusion devices. Medicare also covers certain drugs used in association with organ transplantation, dialysis, chemotherapy, and pain management. Additionally, the program covers certain vaccines, such as those for influenza and hepatitis B. Medicare beneficiaries are responsible for paying a 20 percent copayment on these drugs. Medicare and its beneficiaries paid approximately \$3.9 billion for prescription drugs in 1999.

Physicians and suppliers usually bill Medicare directly for the prescription drugs they provide to beneficiaries. The Health Care Financing Administration (HCFA), which administers the Medicare program, contracts with local carriers and four DME regional carriers (DMERCs) to process Part B claims and establish a reimbursement amount for covered drugs based on Medicare's reimbursement methodology.

Medicare's current reimbursement methodology for prescription drugs is defined by Section 4556 of the Balanced Budget Act of 1997. The HCFA requires carriers to base their reimbursement amount for a covered drug on its average wholesale price (AWP) as published in *Drug Topics Red Book* or similar pricing publications used by the pharmaceutical industry. If a drug is available only in brand form, reimbursement is calculated by taking 95 percent of the drug's AWP. For drugs that have both brand and generic sources available, reimbursement is based on 95 percent of the median AWP for generic sources. However, if a brand name product's AWP is lower than the median generic AWP, Medicare reimburses 95 percent of the lowest brand AWP.

Department of Veterans Affairs Drug Reimbursement

Unlike Medicare, the Department of Veterans Affairs (VA) purchases drugs for its healthcare system directly from manufacturers or wholesalers. There are several purchase options available to the VA, including the Federal Supply Schedule (FSS), Blanket Purchase Agreements, and VA national contracts.

The FSS provides agencies like the VA with a simple process for purchasing commonly-used products in various quantities while still obtaining the discounts associated with volume buying. Using competitive procedures, contracts are awarded to companies to provide services and supplies at the FSS price over a given period of time. Agencies are not required to use the Federal Supply Schedule, however, and are sometimes able to negotiate prices lower than the FSS price.

Sources of Prescription Drugs for Physicians and Suppliers

Physicians and suppliers can purchase drug products through closed pharmacies, group purchasing organizations (GPOs), wholesalers, and directly from manufacturers. Closed pharmacies purchase pharmaceuticals from manufacturers and wholesalers and in turn sell the products to healthcare providers. Generally, closed pharmacies do not dispense drugs to the public. Group purchasing organizations provide their members with lower cost products by negotiating prices for specific drugs from manufacturers. The member can then purchase drugs at the negotiated price either directly from the manufacturer or from a wholesaler who accepts the GPO's price. Wholesalers purchase large volumes of drugs from manufacturers and sell them directly to physicians, suppliers, and pharmacies.

Medicaid Drug Reimbursement

Each State Medicaid agency has the authority to develop its own drug reimbursement methodology subject to upper limits set by HCFA. Like Medicare, most Medicaid agencies use a discounted average wholesale price as the basis for calculating drug reimbursement amounts. Medicaid agencies generally use a more deeply-discounted average wholesale price than does Medicare. Additionally, Medicaid receives rebates from drug manufacturers as required by Federal law. In 1999, the quarterly rebate for brand-name drugs was based on either 15.1 percent of the average manufacturer price (AMP) or the difference between the AMP and the best price, whichever was greater. The AMP is the average price paid by wholesalers for products distributed for retail trade. The best price is the lowest price paid by any purchaser with the exception of Federal agencies and State pharmaceutical assistance programs. The rebate amount for generic drugs was 11 percent of AMP.

Recent Attempts to Lower Medicare Reimbursement

Section 4316 of the Balanced Budget Act of 1997 allows HCFA to diverge from the statutorily-defined payment method if the method results in payment amounts which are not inherently reasonable. In late 1998, HCFA attempted to use this authority to lower what it considered excessive reimbursement for several items. One drug, albuterol, was targeted for an 11 percent fee reduction. However, before any of the lower prices could be implemented, Congress suspended the use of inherent reasonableness through a provision of the Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999. This provision required the General Accounting Office (GAO) to complete a study on the potential effects of using inherent reasonableness measures before HCFA could invoke the authority. The GAO report, issued on July 5, 2000, found that inherent

reasonableness reductions for some items were justified. However, the GAO questioned the methodology the DMERCs used in their collection of pricing data for albuterol sulfate.

The HCFA has also included several nebulizer drugs in a competitive bidding project in Texas which seeks to use market forces to set accurate prices for DME and related supplies. In November 2000, HCFA announced the selection of DME suppliers who had submitted competitive bids for the included items. New prices for these items will go into effect beginning February 1, 2001. According to HCFA, the new reimbursement amounts for the effected nebulizer drugs are approximately 26 percent below the typical Medicare price. The HCFA hopes to use the results from these demonstrations more generally in the Medicare program.

On May 31, 2000, HCFA announced plans for Medicare to utilize newly available AWP's developed for Medicaid as a result of Department of Justice (DOJ) investigations. The DOJ obtained the pricing data from several drug wholesale catalogs, and provided it to First Databank, publisher of a pricing compendium used by the pharmaceutical industry. The HCFA estimated that the 50 drugs identified by the DOJ represented approximately one-third of Medicare payments for prescription drugs. However, legislation passed by Congress on December 21, 2000 required GAO to complete a comprehensive drug pricing study before HCFA could begin using the new lower prices.

Physician Concerns About Reimbursement

Some physician groups have raised concerns about Medicare's attempts to lower reimbursement for prescription drugs. For example, some state that Medicare does not adequately reimburse physicians for the practice costs associated with providing treatment to cancer patients. These physician groups assert that overpayments for prescription drugs simply make up for inadequate payments for other practice costs. While we agree that physicians need to be properly reimbursed for patient care, the analysis of such practice costs is beyond the scope of this study. We believe, however, that the use of inflated drug prices is an inappropriate way for Medicare to address this issue.

Related Work by the Office of Inspector General

The Office of Inspector General (OIG) has studied a number of issues relating to Medicare reimbursement of prescription drugs. Brief summaries of selected studies are presented in Appendix A.

METHODOLOGY

We collected data from five sources. We accessed HCFA's National Claims History file and obtained Medicare drug payment and utilization data for 1999. We contacted Medicare carriers to determine current Medicare reimbursement amounts for covered drugs. We obtained drug payment amounts from the VA and physician/supplier pricing

information from various drug catalogs. We collected Medicaid drug rebate data from HCFA's Medicaid Drug Rebate Initiative system.

Selecting Drugs for Review

Medicare identifies covered drugs using HCFA's Common Procedure Coding System (HCPCS). The HCPCS codes define the type of drug and, in most cases, a dosage amount. Initially, we focused our study on the 30 HCPCS codes with the highest total Medicare payments in 1999. These 30 codes represented 85 percent of the \$3.9 billion in total Medicare payments for drugs in 1999.

We removed several of the 30 HCPCS codes from our review. We removed code J9999 because it is defined as "not otherwise classified, antineoplastic drug." We also removed any HCPCS code which did not have pricing information available from each source (VA, Medicaid, and drug catalogs). Five drugs were removed because they did not meet the three-source criteria: J1561, J7190, J7192, J7320, and J7502. The 24 remaining HCPCS codes accounted for 79 percent (\$3.1 billion) of the \$3.9 billion in Medicare payments for prescription drugs in 1999. Claims for 21 of the 24 codes are processed by local carriers. These drugs would most likely be purchased and administered by physicians. The remaining three drugs are used with a piece of DME called a nebulizer and would most likely be provided by a DME supplier or pharmacy. Claims for these drugs are processed by the DMERCs. A final list of the 24 HCPCS codes under review and their definitions is presented in Appendix B.

Medicare Reimbursement

Because Medicare does not have uniform national reimbursement amounts for prescription drugs, we collected reimbursement information from various carriers. We obtained second-quarter 2000 reimbursement amounts for the 21 HCPCS codes covered by local carriers. We collected this information by contacting the 10 carriers with the highest utilization for these drugs in 1999. We also received Medicare reimbursement amounts from the four DMERCs for the three nebulizer drugs in our review. To determine a single Medicare allowed amount, we calculated median prices for each HCPCS code based on this information. Tables listing the carriers and DMERCs and their reimbursement amounts for the HCPCS codes are presented in Appendix C.

Matching HCPCS Codes to National Drug Codes

Unlike Medicare, Medicaid and the VA use national drug codes (NDCs) rather than HCPCS codes to identify drugs products. Because of these coding differences, we used the January 2000 CD-ROM edition of *Drug Topics Red Book* to identify the specific NDCs that would match the HCPCS code definition for each drug. Every drug manufactured or distributed in the United States has a unique NDC. The NDCs identify the manufacturer of the drug, the product dosage form, and the package size. From the NDCs, drugs can be identified as either brand or generic. Whenever possible, we selected NDCs that met the exact dosage defined in the HCPCS code description. When this was not possible, we chose NDCs with doses where a conversion factor to the

HCPCS definition could be readily determined. Several HCPCS had only one equivalent NDC, while others had 10 or more matches.

VA Pricing

We obtained a file from the VA containing second-quarter 2000 contract acquisition costs. We selected the Federal Supply Schedule price for comparison purposes; however, some drugs had lower prices available to the VA based on other contractual methods. If the dosage of an NDC did not meet the HCPCS definition, we used a conversion factor to ensure that the VA price and Medicare price were for equivalent amounts. We then determined a single VA price for each HCPCS code by calculating the median price for its corresponding NDCs.

Physician/Supplier Drug Costs

To determine actual wholesale prices for the top drugs, we reviewed year 2000 print and online catalogs from five drug wholesalers and one group purchasing organization. The six pricing sources we used provide pharmaceutical products to physician practices and closed pharmacies. We decided that each HCPCS code under review must have prices for matching NDCs in at least three of the six catalogs. If the dosage of an NDC did not meet the HCPCS definition, we used a conversion factor to ensure that the catalog price and Medicare price were for equivalent amounts. We then computed a single catalog price for each HCPCS codes by calculating the median price for its corresponding NDCs.

Medicaid Rebates

We accessed the Medicaid Drug Rebate Initiative system to determine the Medicaid rebate amounts for each drug. We used the fourth quarter 1999 rebate amounts for each NDC code. For many NDCs, the listed rebate was for a dosage amount which was different than the HCPCS dosage amount. In these cases, a conversion factor was used to calculate a rebate for the equivalent dosage. We then computed a single rebate amount for each HCPCS code by calculating the median rebate for its corresponding NDCs.

Calculating Potential Medicare Savings

To calculate potential Medicare savings, we compared Medicare's reimbursement amount for the 24 HCPCS codes to amounts available through the VA and wholesale drug catalogs. We determined the percentage difference in prices by subtracting the source price from the Medicare price, and then dividing this number by the Medicare price. These percentages indicate how much Medicare would save if reimbursement for each drug was based on prices available through the other sources. We then multiplied these percentages by Medicare's 1999 total payment for each HCPCS code to calculate dollar savings. To determine potential savings based on Medicaid rebates, we divided the median Medicaid rebate amount for each drug by its Medicare reimbursement amount. We then multiplied the result by Medicare's 1999 total payment for each HCPCS code to calculate dollar savings.

FINDINGS

Medicare and its beneficiaries would save \$1.6 billion a year if 24 drugs were reimbursed at amounts available to the VA

Medicare spending for 24 drugs would be cut in half if Medicare reimbursement amounts equaled VA cost

After comparing the median Medicare reimbursement amount with the corresponding median VA acquisition cost for 24 drugs, we estimate that Medicare and its beneficiaries would save \$1.6 billion a year if Medicare's reimbursement amounts for the drugs equaled prices obtained by the VA under the Federal Supply Schedule. These savings represent 52 percent of the \$3.1 billion that Medicare and its beneficiaries paid for these 24 drugs in 1999.

The estimated savings for individual drugs ranged from a high of \$351 million for J9217 (leuprolide acetate) to a low of \$9.4 million for J9390 (vinorelbine tartrate). Drugs with estimated annual savings greater than \$50 million are listed in Table 1. A complete list of the 24 drugs, Medicare reimbursement, VA costs, and potential savings is provided in Appendix D.

Table 1: Drugs with Estimated Savings Over \$50 Million a Year

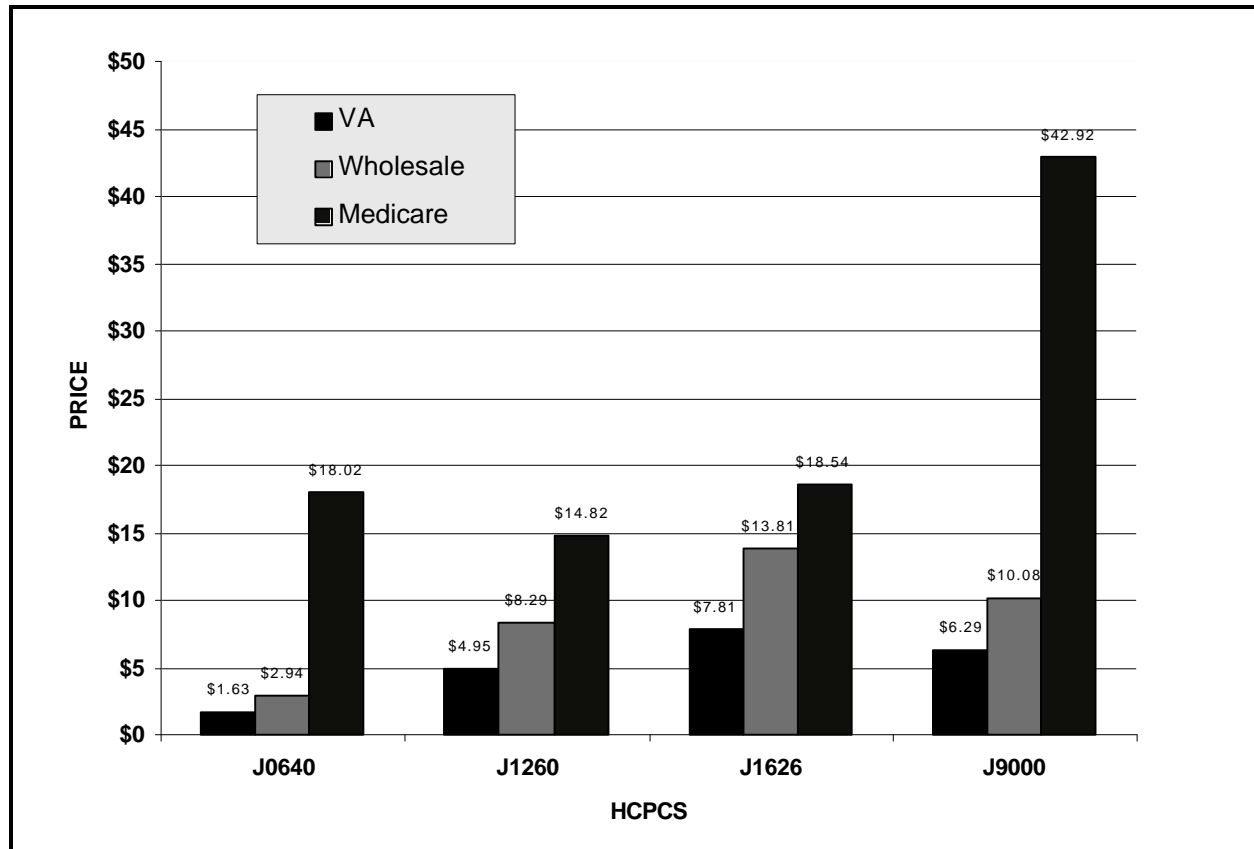
HCPSC CODE	GENERIC DRUG NAME	MEDICARE MEDIAN	VA MEDIAN	PERCENT SAVINGS	1999 ALLOWED CHARGES	ESTIMATED MEDICARE SAVINGS
J9217	Leuprolide acetate, 7.5 mg	\$592.60	\$257.00	56.6%	\$620,102,889	\$351,175,379
J7619	Albuterol, per mg	\$0.47	\$0.07	85.1%	\$246,136,877	\$209,478,193
J7644	Ipratropium bromide, per mg	\$3.34	\$.84	74.9%	\$250,916,635	\$187,811,853
J9202	Goserelin acetate, 3.6 mg	\$446.49	\$214.87	51.9%	\$321,485,273	\$166,772,870
Q0136	Epoetin alpha, 1000 units	\$11.40	\$7.22	36.7%	\$379,708,697	\$139,226,522
J9265	Paclitaxel, 30 mg	\$173.49	\$107.59	38.0%	\$249,940,717	\$94,939,727
J9045	Carboplatin, 50 mg	\$101.37	\$41.14	59.4%	\$116,254,013	\$69,073,485
J0640	Leucovorin calcium, 50 mg	\$18.02	\$1.63	91.0%	\$66,740,227	\$60,703,236

The VA paid between 15 and 91 percent less than the Medicare reimbursement amount for the 24 drugs reviewed

Medicare reimbursement amounts were greater than VA cost for every drug in our review. However, there was substantial variation in the difference between Medicare reimbursement and VA cost among the 24 drugs. Twelve of the drugs in our study had Medicare reimbursement amounts that were more than double the VA price. For six of these drugs, Medicare reimbursed between 3 and 11 times the VA price. The difference between Medicare reimbursement and VA cost was less than 20 percent for only two of

the 24 drugs. Furthermore, several drugs had even lower prices available to the VA through other contractual methods. A comparison of Medicare reimbursement amounts, VA costs, and actual wholesale prices for selected drugs appears in Chart 1.

Chart 1: Price Comparisons for Selected Drugs



Medicare and its beneficiaries would save \$761 million a year by paying the actual wholesale price for 24 drugs

Medicare spending for 24 drugs would be reduced by one-fourth if Medicare reimbursement amounts equaled prices available to physicians and suppliers

We estimate that Medicare payments for 24 drugs exceeded actual wholesale prices by \$761 million a year. This represents 25 percent of the \$3.1 billion Medicare and its beneficiaries reimbursed for these drugs in 1999. The difference between catalog prices and Medicare reimbursement amounts for J9217 (leuprolide acetate) accounted for almost \$100 million in potential savings. Furthermore, if Medicare reimbursed only the three nebulizer drugs in our study (J7608, J7619, J7644) based on actual wholesale prices rather than AWP, the program would save over \$325 million a year. A complete list of the 24 drugs, Medicare reimbursement, catalog prices, and potential savings is provided in Appendix E.

Actual wholesale prices were between 6 and 84 percent below Medicare reimbursement amounts for 24 drugs

Medicare reimbursement amounts were greater than catalog prices for every drug in our review. However, there were significant differences between Medicare reimbursement amounts and actual wholesale prices for many drugs. Four of the drugs in our study had Medicare reimbursement amounts that were more than double the median catalog price. One of these drugs had a Medicare reimbursement amount more than six times higher than the median catalog price. A chart illustrating Medicare reimbursement amounts, VA costs, and actual wholesale prices for selected drugs appears on the previous page.

Medicare would save over \$425 million a year on 24 drugs by using Medicaid's rebate program

We estimate that Medicare would save \$429 million a year on 24 drugs by collecting rebates equal to those negotiated by the Medicaid program. These rebates would lower Medicare spending on these 24 drugs by almost 15 percent. Medicare would save more than \$50 million on both J9217 (leuprolide acetate) and Q0136 (epoetin alfa, non-ESRD) by utilizing the Medicaid rebate. Seven of the 24 drugs under review had Medicaid rebates that would discount the Medicare reimbursement amount by more than 30 percent.

Carriers are not establishing consistent drug reimbursement amounts for certain drugs

Medicare's reimbursement methodology states that covered drugs are reimbursed at 95 percent of AWP; therefore, geographical considerations are not taken into account. However, we found differences in the reimbursement amounts between local carriers. There was no variation in the reimbursement amounts for the three drugs reimbursed by the DMERCs.

For some HCPCS codes, the difference in prices between local carriers was significant. Six of the 21 drugs with carrier-established reimbursement amounts had more than a 10 percent difference between the lowest and highest reimbursement amount. The most egregious was J0640 (leucovorin calcium), with one carrier reimbursing \$17.51 and another reimbursing \$35.47. Pricing for J9000 (doxorubicin) also varied greatly, with reimbursement amounts ranging from \$38.03 to \$52.44. Drugs which had more than a 10 percent price variation between carriers are listed in Table 2 on page 9. A table listing the carriers and DMERCs and their reimbursement amount for all 24 HCPCS codes is presented in Appendix C.

Table 2: Variation in Medicare Prices for Selected Drugs

HCPSC Code	Generic Drug Name	Median Medicare Amount	Minimum Medicare Amount	Maximum Medicare Amount	Difference Between Minimum and Maximum Amount
J0640	Leucovorin Calcium	\$18.02	\$17.51	\$35.47	102.6%
J1562	Immune Globulin	\$396.63	\$380.00	\$439.38	15.6%
J2820	Sargromostim	\$27.41	\$23.95	\$27.42	14.5%
J9000	Doxorubicin HCl	\$42.92	\$38.03	\$52.44	37.9%
J9217	Leuprolide Acetate	\$592.60	\$564.65	\$623.79	10.5%
J9350	Topotecan	\$573.75	\$546.44	\$602.44	10.2%

Inconsistency in drug reimbursement amounts among Medicare carriers is not a new problem. A previous OIG report released in December 1997, *Excessive Medicare Payments for Prescription Drugs*, found similar variations. This previous report identified three likely causes for pricing discrepancies: (1) decisions regarding when to update reimbursement amounts, (2) the choice of pricing compendia used to determine AWP, and (3) the selection of particular NDCs to meet the HCPSC code definition.

R E C O M M E N D A T I O N S

The HCFA should reduce excessive Medicare drug reimbursement amounts

Despite numerous attempts by HCFA to lower Medicare drug reimbursement, the findings of this report illustrate once again that Medicare simply pays too much for prescription drugs. The published AWP's that Medicare carriers currently use to establish reimbursement amounts bear little or no resemblance to actual wholesale prices that are available to physicians, suppliers, and other large government purchasers. We believe that HCFA's attempts to use the more accurate AWP's supplied by First Databank is a significant first step towards reimbursing drugs in a more appropriate manner. However, we believe that HCFA should continue to seek additional administrative and legislative remedies to reduce excessive drug reimbursement amounts.

We believe there are a number of options available to HCFA for implementing this recommendation, including: (1) continuing to collect more accurate average wholesale prices from drug pricing catalogs, (2) basing payment on physician/supplier acquisition costs, (3) establishing manufacturers' rebates similar to those used in the Medicaid program, (4) creating a fee schedule for covered drugs based on Department of Veterans Affairs prices, and (5) utilizing the inherent reasonableness authority.

The HCFA should require all carriers to reimburse a uniform amount for each drug

We believe that the pricing differences among local carriers for individual drug codes is problematic. The amount which physicians and suppliers are reimbursed for drugs should not depend on which carrier they bill. The DMERCs have been able to adopt uniform pricing for the drugs which they cover, and we expect that local carriers should be able to do the same. In a 1997 report which noted similar problems, we recommended two options to correct pricing differences: (1) the HCFA could supply all carriers with list of average wholesale prices that it has determined represent each drug code, or (2) the HCFA could contract with a single entity to calculate drug reimbursement amounts and then distribute the amounts to each carrier. We continue to recommend that HCFA undertake one of these options.

Agency Comments

The HCFA concurred with our recommendation that reimbursement amounts for Medicare-covered drugs should be lowered, noting that the current AWP-based reimbursement method creates incentives for price inflation, distorts clinical decisions, and cheats taxpayers. The HCFA also explained that some providers now rely on inflated drug payments to cover other practice expenses. The HCFA believes that any price reductions need to take these expenses into account. Nevertheless, the HCFA strongly agreed that the payment of inflated drug prices is an inappropriate way to compensate practitioners and suppliers for inadequate reimbursement of other practice costs.

The HCFA also agreed with our recommendation that Medicare carriers should be required to reimburse uniform amounts for covered drugs. The full text of HCFA's comments is presented in Appendix F.

APPENDIX A

Previous OIG Reports on Medicare Drug Reimbursement

Medicare Reimbursement of Albuterol (OEI-03-00-00311), June 2000. We found that Medicare and its beneficiaries would save \$120 million or \$209 million a year if albuterol was reimbursed at amounts available through Medicaid and the VA, respectively. Medicare and its beneficiaries would save \$47 million or \$115 million a year if Medicare reimbursed albuterol at prices available at chain and Internet pharmacies.

Medicare Reimbursement of End Stage Renal Disease Drugs (OEI-03-00-00020), June 2000. We found that Medicare reimbursement amounts would be nearly halved for five ESRD drugs if amounts were based on VA acquisition costs. In addition, Medicare would save between 5 and 38 percent if its reimbursement amounts were equal to Medicaid reimbursement including rebates.

Comparing Drug Reimbursement: Medicare and the Department of Veterans Affairs (OEI-03-97-00293), November 1998. We found that Medicare and its beneficiaries would save \$1 billion in 1998 if the allowed amounts for 34 drugs were equal to prices obtained by the VA. Furthermore, Medicare allowed between 15 and 1600 percent more than the VA for the 34 drugs reviewed.

Are Medicare Allowances for Albuterol Sulfate Reasonable? (OEI-03-97-00292), August 1998. We found that Medicare would allow between 56 to 550 percent more than the VA would pay for generic versions of albuterol sulfate in 1998, and 20 percent more than the average Medicaid payment for albuterol sulfate in 1997. Additionally, Medicare allowed 333 percent more than available acquisition costs for the drug in 1998. Customers of mail-order pharmacies would pay up to 30 percent less than Medicare for albuterol sulfate in 1998.

The Impact of High-Priced Generic Drugs on Medicare and Medicaid (OEI-03-97-00510), July 1998. We found that Medicare and its beneficiaries could have saved between \$5 million and \$12 million for four drugs if reimbursement had not been based on higher-priced generic versions. Florida's Medicaid program would have saved half a million dollars for eight drugs in 1996 if higher-priced generic drugs had been reimbursed at brand prices.

Excessive Medicare Payments for Prescription Drugs (OEI-03-97-00290), December 1997. We found that Medicare allowances for 22 drugs exceeded actual wholesale prices by \$447 million in 1996. For more than one-third of the 22 drugs reviewed, Medicare allowed amounts were more than double the actual wholesale prices available to physicians and suppliers. Furthermore, we found that there was no consistency among Medicare carriers in establishing and updating drug reimbursement amounts.

APPENDIX A***Appropriateness of Medicare Prescription Drug Allowances (OEI-03-96-00420), May 1996.***

We found that under a drug rebate program similar to Medicaid's, Medicare would have saved \$122 million for 17 prescription drugs in 1994. Medicare could have saved an additional \$144 million in 1994 had the program employed a discounted AWP drug reimbursement formula. We also found that the lack of an NDC-based billing system would prevent HCFA from taking advantage of rebates and other discounted reimbursement formulas.

A Comparison of Albuterol Sulfate Prices (OEI-03-94-00392), June 1996. We found that many of the pharmacies surveyed charged customers less than the Medicare allowed amount for generic albuterol sulfate. The five buying groups surveyed had negotiated prices between 56 and 70 percent lower than Medicare's reimbursement amount for the drug.

Suppliers' Acquisition Costs for Albuterol Sulfate (OEI-03-94-00393), June 1996. We found that Medicare's allowances for albuterol sulfate substantially exceeded suppliers' acquisition costs for the drug, and that the program could have saved \$94 million during the 14-month review period if Medicare reimbursement amounts had been based on average supplier invoice costs.

Medicare Payments for Nebulizer Drugs (OEI-03-94-00390), February 1996. We found that Medicare and its beneficiaries paid about \$37 million more for three nebulizer drugs in 17 states than Medicaid would have paid for equivalent drugs. In addition, we found that the potential savings were not limited to the three nebulizer drugs and 17 states which were reviewed.

APPENDIX B**Description of 24 HCPCS Codes**

2000 HCPCS CODE	1999 HCPCS CODE	DESCRIPTION
J0640	J0640	Injection, Leucovorin Calcium, per 50 mg
J1260	J1260	Injection, Dolasetron Mesylate, 10 mg
J1440	J1440	Injection, Filgrastim (G-CSF), 300 mcg
J1441	J1441	Injection, Filgrastim (G-CSF), 480 mcg
J1562	J1562	Injection, Immune Globulin, intravenous, 5 g
J1626	J1626	Injection, Granisetron Hydrochloride, per 100 mcg
J2405	J2405	Injection, Ondansetron HCl, per 1 mg
J2430	J2430	Injection, Pamidronate Disodium, per 30 mg
J2820	J2820	Injection, Sargramostim (GM-CSF), 50 mcg
J7608*	K0503	Acetylcysteine, unit dose form, per gram
J7619*	K0505	Albuterol Sulfate, unit dose form, per mg
J7644*	K0518	Ipratropium Bromide, unit dose form, per mg
J9000	J9000	Injection, Doxorubicin HCl, 10 mg
J9045	J9045	Injection, Carboplatin, 50 mg
J9170	J9170	Injection, Docetaxel, 20 mg
J9201	J9201	Injection, Gemcitabine HCl, 200 mg
J9202	J9202	Goserelin Acetate implant, per 3.6 mg
J9206	J9206	Injection, Irinotecan, 20 mg
J9217	J9217	Leuprolide Acetate (for depot suspension), 7.5 mg
J9265	J9265	Injection, Paclitaxel, 30 mg
J9310	J9310	Injection, Rituximab, 100 mg
J9350	J9350	Injection, Topotecan, 4 mg
J9390	J9390	Vinorelbine Tartrate, per 10 mg
Q0136	Q0136	Injection, Epoetin Alpha, (non-ESRD), per 1000 units

* New HCPCS codes for nebulizer drugs took affect January 1, 2000.

APPENDIX C**Medicare Carrier Reimbursement Amounts**

HCPCS	FL	TX	PA	CA	WI	NY	OH	NJ	TN	IL
J0640	\$35.47	\$20.45	\$17.51	\$17.52	\$18.02	\$18.51	\$18.02	\$18.51	\$17.93	\$18.02
J1260	\$15.81	\$15.82	\$14.80	\$14.80	\$14.82	\$15.81	\$14.82	\$15.81	\$14.70	\$14.82
J1440	\$171.38	\$164.21	\$171.38	\$171.38	\$171.38	\$168.00	\$171.38	\$168.00	\$171.38	\$171.38
J1441	\$273.03	\$261.58	\$273.03	\$273.03	\$273.03	\$273.03	\$273.03	\$273.03	\$273.03	\$273.03
J1562	\$380.00	\$439.38	\$413.25	\$380.00	\$427.98	\$380.00	\$380.00	\$380.00	\$413.25	\$427.98
J1626	\$18.54	\$18.54	\$18.54	---	\$18.54	\$18.54	\$18.54	\$18.54	\$17.67	\$18.54
J2405	\$6.08	\$6.09	\$6.08	\$6.09	\$6.10	\$6.08	\$6.10	\$6.08	\$5.94	\$6.10
J2430	\$253.20	\$253.21	\$232.51	\$232.51	\$253.20	\$233.91	\$253.20	\$233.91	\$232.51	\$253.20
J2820	\$27.41	\$24.60	\$25.62	\$23.95	\$27.42	\$27.41	\$27.42	\$27.41	\$27.41	\$27.42
J9000	\$42.81	\$50.96	\$52.44	\$50.96	\$42.82	\$43.02	\$42.82	\$43.02	\$38.03	\$42.82
J9045	\$103.84	\$94.96	\$98.90	\$103.84	\$103.84	\$98.90	\$103.84	\$98.90	\$98.90	\$103.84
J9170	\$283.65	\$283.65	\$270.14	\$283.65	\$283.65	\$283.65	\$283.65	\$283.65	\$270.14	\$283.65
J9201	\$88.46	\$88.46	\$88.46	\$88.46	\$88.46	\$88.46	\$88.46	\$88.46	\$88.46	\$88.46
J9202	\$446.49	\$446.49	\$446.49	\$446.49	\$446.49	\$446.49	\$446.49	\$446.49	\$446.49	\$446.49
J9206	\$117.81	\$117.81	\$110.10	\$117.81	\$117.82	\$117.81	\$117.82	\$117.81	\$117.81	\$117.82
J9217	\$564.91	\$565.93	\$564.65	\$623.79	\$592.60	\$592.60	\$592.60	\$592.60	\$564.92	\$592.60
J9265	\$173.49	\$166.58	\$173.48	\$173.50	\$173.50	\$173.49	\$173.50	\$173.49	\$173.49	\$173.50
J9310	\$420.28	\$420.29	\$420.28	\$420.29	\$420.29	\$420.28	\$420.29	\$420.28	\$420.28	\$420.29
J9350	\$602.44	\$602.44	\$573.75	\$573.75	\$573.75	\$602.44	\$573.75	\$602.44	\$546.44	\$573.75
J9390	\$75.50	\$72.49	\$68.99	\$75.51	\$75.51	\$75.50	\$75.51	\$75.50	\$75.50	\$75.51
	\$11.84	---	\$12.00	\$11.62	\$11.40	\$11.40	\$11.40	\$11.40	\$11.40	\$11.40

HCPCS	DMERC A	DMERC B	DMERC C	DMERC D	MEDIAN
J7608	\$5.05	\$5.05	\$5.05	\$5.05	\$5.05
J7619	\$0.47	\$0.47	\$0.47	\$0.47	\$0.47
J7644	\$3.34	\$3.34	\$3.34	\$3.34	\$3.34

APPENDIX D

Medicare Savings Based on Department of Veterans Affairs Prices

HCPDS CODE	GENERIC DRUG NAME	MEDICARE MEDIAN	VA MEDIAN	PERCENT SAVINGS*	1999 ALLOWED CHARGES	ESTIMATED MEDICARE SAVINGS
J0640	Leucovorin Calcium, 50 mg	\$18.02	\$1.63	91.0%	\$66,740,227	\$60,703,236
J1260	Dolasetron Mesylate, 10 mg	\$14.82	\$4.95	66.6%	\$46,647,272	\$31,066,705
J1440	Filgrastim, 300 mcg	\$171.38	\$130.72	23.7%	\$47,893,675	\$11,362,801
J1441	Filgrastim, 480 mcg	\$273.03	\$208.23	23.7%	\$67,411,261	\$15,999,157
J1562	Immune Globulin, 5g	\$396.63	\$110.54	72.1%	\$43,239,398	\$31,188,663
J1626	Granisetron HCl, 100 mcg	\$18.54	\$7.81	57.9%	\$46,432,246	\$26,872,600
J2405	Ondansetron HCl, 1 mg	\$6.09	\$3.94	35.3%	\$47,721,885	\$16,847,628
J2430	Pamidronate Disodium, 30 mg	\$243.56	\$203.45	16.5%	\$112,916,846	\$18,595,396
J2820	Sargramostim, 50 mcg	\$27.41	\$10.06	63.3%	\$23,533,251	\$14,896,093
J7608	Acetylcysteine, per g	\$5.05	\$1.50	70.3%	\$35,908,222	\$25,242,413
J7619	Albuterol Sulfate, per mg	\$0.47	\$0.07	85.1%	\$246,136,877	\$209,478,193
J7644	Ipratropium Bromide, per mg	\$3.34	\$0.84	74.9%	\$250,916,635	\$187,811,853
J9000	Doxorubicin HCl, 10 mg	\$42.92	\$6.29	85.3%	\$27,831,805	\$23,753,006
J9045	Carboplatin, 50 mg	\$101.37	\$41.14	59.4%	\$116,254,013	\$69,073,485
J9170	Docetaxel, 20 mg	\$283.65	\$151.77	46.5%	\$58,661,193	\$27,273,887
J9201	Gemcitabine HCl, 200 mg	\$88.46	\$74.86	15.4%	\$75,256,901	\$11,570,132
J9202	Goserelin Acetate, 3.6 mg	\$446.49	\$214.87	51.9%	\$321,485,273	\$166,772,870
J9206	Irinotecan, 20 mg	\$117.81	\$75.45	36.0%	\$79,914,022	\$28,734,046
J9217	Leuprolide Acetate, 7.5 mg	\$592.60	\$257.00	56.6%	\$620,102,889	\$351,175,379
J9265	Paclitaxel, 30 mg	\$173.49	\$107.59	38.0%	\$249,940,717	\$94,939,727
J9310	Rituximab, 100 mg	\$420.29	\$239.58	43.0%	\$71,072,780	\$30,558,810
J9350	Topotecan, 4 mg	\$573.75	\$307.25	46.5%	\$31,504,581	\$14,633,500
J9390	Vinorelbine Tartrate, 10 mg	\$75.50	\$46.20	38.8%	\$24,325,270	\$9,440,138
Q0136	Epoetin Alfa, per 1000 units	\$11.40	\$7.22	36.7%	\$379,708,697	\$139,226,522
TOTAL FOR 24 HCPDS					\$3,091,555,936	\$1,617,216,241

* To determine percent savings, we subtracted the VA price from the Medicare reimbursement amount. We then divided this number by the Medicare reimbursement amount.

APPENDIX E**Medicare Savings Based on Physician/Supplier Costs**

HCPDS CODE	GENERIC DRUG NAME	MEDICARE MEDIAN	CATALOG MEDIAN	PERCENT SAVINGS*	1999 ALLOWED CHARGES	ESTIMATED MEDICARE SAVINGS
J0640	Leucovorin Calcium, 50 mg	\$18.02	\$2.94	83.7%	\$66,740,227	\$55,851,422
J1260	Dolasetron Mesylate, 10 mg	\$14.82	\$8.29	44.1%	\$46,647,272	\$20,553,758
J1440	Filgrastim, 300 mcg	\$171.38	\$144.30	15.8%	\$47,893,675	\$7,567,748
J1441	Filgrastim, 480 mcg	\$273.03	\$229.90	15.8%	\$67,411,261	\$10,648,821
J1562	Immune Globulin, 5g	\$396.63	\$300.00	24.4%	\$43,239,398	\$10,534,309
J1626	Granisetron HCl, 100 mcg	\$18.54	\$13.81	25.5%	\$46,432,246	\$11,845,983
J2405	Ondansetron HCl, 1 mg	\$6.09	\$5.49	9.9%	\$47,721,885	\$4,701,664
J2430	Pamidronate Disodium, 30 mg	\$243.56	\$223.26	8.3%	\$112,916,846	\$9,411,283
J2820	Sargramostim, 50 mcg	\$27.41	\$23.13	15.6%	\$23,533,251	\$3,674,656
J7608	Acetylcysteine, per g	\$5.05	\$3.38	33.1%	\$35,908,222	\$11,874,600
J7619	Albuterol Sulfate, per mg	\$0.47	\$0.13	72.3%	\$246,136,877	\$178,056,464
J7644	Ipratropium Bromide, per mg	\$3.34	\$1.53	54.2%	\$250,916,635	\$135,975,781
J9000	Doxorubicin HCl, 10 mg	\$42.92	\$10.08	76.5%	\$27,831,805	\$21,295,351
J9045	Carboplatin, 50 mg	\$101.37	\$87.79	13.4%	\$116,254,013	\$15,573,932
J9170	Docetaxel, 20 mg	\$283.65	\$238.86	15.8%	\$58,661,193	\$9,262,947
J9201	Gemcitabine HCl, 200 mg	\$88.46	\$74.49	15.8%	\$75,256,901	\$11,884,907
J9202	Goserelin Acetate, 3.6 mg	\$446.49	\$375.99	15.8%	\$321,485,273	\$50,761,969
J9206	Irinotecan, 20 mg	\$117.81	\$98.63	16.3%	\$79,914,022	\$13,010,364
J9217	Leuprolide Acetate, 7.5 mg	\$592.60	\$499.03	15.8%	\$620,102,889	\$97,912,635
J9265	Paclitaxel, 30 mg	\$173.49	\$146.10	15.8%	\$249,940,717	\$39,459,774
J9310	Rituximab, 100 mg	\$420.29	\$353.93	15.8%	\$71,072,780	\$11,221,751
J9350	Topotecan, 4 mg	\$573.75	\$507.32	11.6%	\$31,504,581	\$3,647,668
J9390	Vinorelbine Tartrate, 10 mg	\$75.50	\$64.11	15.1%	\$24,325,270	\$3,669,733
Q0136	Epoetin Alfa, per 1000 units	\$11.40	\$10.72	6.0%	\$379,708,697	\$22,649,291
TOTAL FOR 24 HCPDS					\$3,091,555,936	\$761,046,810

* To determine percent savings, we subtracted the catalog price from the Medicare reimbursement amount. We then divided this number by the Medicare reimbursement amount.

APPENDIX F

Health Care Financing Administration Comments

APPENDIX F



DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Care Financing Administration

The Administrator
Washington, D.C. 20201

DATE: DEC - 6 2000

TO: June Gibbs Brown
Inspector General

FROM: Michael M. Hash *Michael M. Hash*
Acting Administrator

SUBJECT: Office of Inspector General (OIG) Draft Report: "Medicare Reimbursement of Prescription Drugs," (OEI-03-00-00310).

Thank you for the opportunity to review the above-mentioned draft report. We concur with the OIG that there is a need for lowering the prices Medicare pays providers for the limited number of outpatient prescription drugs that Medicare currently covers. We have already made some strides in this area, though many of our additional proposals to lower inflated prices would require Congressional action.

First and foremost, in attempting to lower the prices Medicare pays providers for drugs, the Health Care Financing Administration (HCFA) recognizes that the payment system that compensates physicians and suppliers based on Average Wholesale Price (AWP) creates a perverse incentive for price inflation. In this system, physicians and suppliers actually make profits when pharmaceutical manufacturers raise their prices, thus distorting clinical decisions and cheating taxpayers.

Indeed, some practitioners have come to rely on inflated drug payments to subsidize associated, non-reimbursed costs, such as storage and administration, and, in some cases, to provide other important services that are not adequately compensated. Consequently, the administrative actions we take to reduce the price of a drug need to take such expenses into account. Nevertheless, we strongly agree with the OIG that the use of inflated drug prices is an inappropriate way to compensate practitioners and suppliers for inadequate reimbursement for other practice costs.

We believe the policy objective should be to pay the right price for the drug as well as the right price for its administration and storage. We believe the correct approach to resolving these problems is to comprehensively address excessive drug prices through legislation, and, at the same time, take regulatory action to ensure that Medicare's provider payment systems appropriately take into account costs for administration and storage.

APPENDIX F

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As you know, our attempts to obtain legislation to pay more accurately for drugs have not been successful. Congress has repeatedly rejected the Administration's legislative proposals to pay on the basis of acquisition costs or to reduce the AWP by 17 percent.

The administrative tools available to us are limited. If we have creditable information that the AWP prices we are using are incorrect, we can provide this information to our contractors; we can also engage in rulemaking. As you know, when we have taken administrative action to reduce payments in the past, we have been blocked by Congress.

For example, we attempted to use the inherent reasonableness authority, as revised in the Balanced Budget Act of 1997 to lower payments for albuterol sulfate. However, Congress suspended that effort until the recently released General Accounting Office study and final rule making on inherent reasonableness.

In addition, this year we attempted to lower Medicare payments for drugs, while taking administrative and legislative steps to increase certain payments to insure access for beneficiaries to these drugs. We transmitted to our Medicare carriers the AWP data obtained by the Department of Justice (DOJ). We asked carriers to consider them for use in their drug pricing updates for those drugs where we believe access would not be compromised. However, the House-passed Medicare, Medicaid, and State Children's Health Insurance Program Benefits Improvement and Protection Act of 2000, H.R. 5543, contains a freeze on changes to the AWP in use by Medicare as of September 1, 2000. This provision would preclude implementation of lower drug prices based on the DOJ data. Because the Medicare carriers must change their systems before the legislative outcome, and in order to avoid disruption from lowering and then raising prices, we have instructed carriers to delay implementation of the DOJ-derived prices until after the outcome of the legislation is clear.

We want to continue to work with OIG and GAO to set reasonable payments for drugs covered by the Medicare program. However, we must recognize that the drug payments are not made in a vacuum, and that program payments for other administrative expenses must be fair and reasonable to ensure that Medicare beneficiaries have access to the drugs that they need. Our specific comments on your recommendations are attached.

Attachment

APPENDIX F**Attachment****Recommendation 1**

The HCFA should reduce excessive Medicare drug reimbursement amounts

HCFA Comment:

We agree. The first option that OIG suggests is to use wholesaler catalog prices. This was the basis for the DOJ data that we sent to carriers. We will continue to explore this approach.

OIG also recommends as other options that HCFA base payment on acquisition cost, on a Medicaid rebate type program, or on a Department of Veterans Affairs type fee schedule. While these options offer considerable promise, each requires legislation. Congress has been unwilling to accept acquisition cost as a basis, and, rather than attempt one of the other approaches OIG suggests, the Administration followed the Congress's lead by proposing a 17 percent reduction from AWP to replace the current 5 percent statutory reduction.

Recommendation 2

The HCFA should require all carriers to reimburse a uniform amount for each drug

HCFA Comment:

We agree that HCFA should move toward greater uniformity in carrier pricing. We have focused on utilizing the best practices used by the Medicare Part B contractors to calculate drug prices in addition to identifying and removing the less-than-best practices. Also, the use of a single computer software program to price drugs is under consideration.